Uptake Rates of Three COVID-19 Vaccine Doses and Risk Factors for Incomplete Vaccination Among Patients With Inflammatory Bowel Disease Residing in Wisconsin: A Single-Center Cohort

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ABSTRACT

Introduction: Patients with inflammatory bowel disease on systemic corticosteroids may be at higher risk of adverse outcomes of COVID-19 infection, and vaccination is an essential preventive measure. Uptake of the original 2-dose COVID-19 messenger RNA (mRNA) primary vaccine series was previously high among patients with inflammatory bowel disease, while uptake of subsequent doses based on interval recommendations made by the Advisory Committee on Immunization Practice remains unknown. Herein, we evaluated uptake of 3 COVID-19 mRNA vaccine doses among patients with inflammatory bowel disease.

Methods: We performed a single-center, retrospective study evaluating COVID-19 vaccine uptake among adult patients with inflammatory bowel disease residing in Wisconsin who were seen at the University of Wisconsin Digestive Health Center. Vaccination status as of April 30, 2022, was verified in the Wisconsin Immunization Registry. A multivariable logistic regression was performed with the primary endpoint of receipt of 3 COVID-19 vaccine doses. Secondary outcomes included identification of demographic and clinical variables associated with incomplete vaccination.

Results: A total of 1012 patients were identified; 728 (71.9%) patients received 3 COVID-19 vaccine doses. Multivariable logistic regression revealed that younger age (odds ratio [OR] 1.02; 95% CI, 1.01–1.03; $P=0.001$), rural status (OR 3.44; 95% CI, 2.17–5.56; $P<0.001$), underrepresented minority status (OR 3.85; 95% CI, 1.89–7.69; $P<0.001$), and absence of influenza vaccination (OR 8.17; 95% CI, 5.41–12.33; $P<0.001$) were significantly associated with incomplete COVID-19 vaccination.

Conclusions: Receipt of 3 COVID-19 mRNA vaccine doses is high overall among patients with inflammatory bowel disease. Younger age, underrepresented race/ethnicity, rural status, and lack of influenza vaccination are associated with incomplete COVID-19 vaccination.

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INTRODUCTION

In the United States, 4 safe and effective vaccines are available that reduce incidence of COVID-19–related hospitalization and death: BNT162b2 (Pfizer-BioNTech, messenger RNA [mRNA]), mRNA-1273 (Moderna, mRNA), JNJ-78436735 (Janssen, viral vector), and NVX-CoV2373 (Novavax, protein subunit).[1] Gastroenterologists provide care for patients with varying degrees of immunosuppression, including patients with inflammatory bowel disease (IBD). Patients with IBD on systemic corticosteroids are at higher risk of severe COVID-19 (eg, intensive care unit admission, mechanical ventilation, death), and vaccination is important to prevent such outcomes.[2]

While COVID-19 vaccines are safe and well tolerated among patients with IBD, they are also effective.[3] Patients with IBD have demonstrated a 95% to 99% humoral immune response rate to a 2-dose COVID-19 mRNA vaccine series and a 100% response rate to 3 doses, and this immune response may be relatively blunted by anti-tumor necrosis factor (anti-TNF) therapy.[4–7]

Moreover, receipt of 3 COVID-19 vaccine doses has been shown to reduce risk of COVID-related hospitalization.[8,9] At the time of this study, the Advisory Committee on Immunization Practices (ACIP) had recommended a 3-dose primary mRNA vaccine series, followed by a booster mRNA vaccine dose 3 months thereafter for those who were considered moderately to severely immunosuppressed.[10] For patients with IBD, this definition includes those on antimetabolites (eg, methotrexate, thiopurines),

anti-TNFs, or systemic corticosteroids. For those who do not fulfill these criteria, the ACIP had otherwise recommended a 2-dose primary mRNA vaccine series followed by a booster mRNA vaccine dose 5 months thereafter.

COVID-19 vaccine uptake is an obvious but fundamental prerequisite to realize the benefits of vaccine-induced immunity and prevent adverse outcomes secondary to infection. Prior reports have established suboptimal uptake of non–COVID-19 vaccines within the IBD population.[11] A previous study analyzing a Wisconsin-based cohort of patients with IBD identified an 84% completion rate of the 2-dose primary series – the prior ACIP recommendation.[12] Significant disparities of age, gender, race/ethnicity, geography, and socioeconomic status with respect to vaccine uptake were identified. Vaccination patterns among US patients with IBD have not been formally evaluated since the advent of a 3-dose series and booster dose.

The purpose of this study was to evaluate COVID-19 vaccination patterns among patients with IBD. The primary outcome was receipt of 3 COVID-19 mRNA vaccine doses. We hypothesized that vaccine uptake would be high, with similar disparities as observed with the original 2-dose primary series.[12] Secondary outcomes included identification of demographic and clinical variables associated with incomplete vaccination.

METHODS

Study Design

We performed a single-center, retrospective study evaluating uptake of 3 COVID-19 vaccine doses among adult patients with IBD. Our cohort comprised patients with IBD who were seen initially at the University of Wisconsin Digestive Health Center from November 1, 2020, through April 30, 2021, as first described in our prior report pertaining to the original 2-dose primary series.[12] In-person, video, and telephone visits were considered eligible encounter types. Exclusion criteria included death during study period, inactive Wisconsin Immunization Registry (WIR) record, residence outside the state of Wisconsin, and address listed as a post office box or correctional center.

Data Collection

Manual chart review was performed and completed by April 30, 2022. The following general variables were extracted from the electronic medical record: age, gender, race, ethnicity, address, smoking status, body mass index (BMI), variables of Charlson Comorbidity Index (CCI), and addressal of patient COVID-19 vaccination status by the provider as documented in the encounter note. Disease-specific data included type and duration of IBD, history of IBD-related surgery (eg, incision and drainage, bowel resection), and current IBD-directed therapy.

Underrepresented minority (URM) was defined as Black, Native Hawaiian/Pacific Islander, American Indian/Alaska Native, Hispanic/Latino. ZIP codes were assigned to 1 of 6 rural-urban geodisparity categories using the Health Innovation Program toolkit: urban advantaged, urban, urban underserved, rural advantaged, rural, or rural underserved.[13] Street-level addresses were used to assign 2018 area deprivation index (ADI) using the Neighborhood Atlas.[14] COVID-19 vaccination was considered addressed by the provider if there was documentation of COVID-19 vaccination status in a clinic encounter note (eg, "fully vaccinated against COVID-19," "declines COVID-19 vaccine").

Wisconsin Immunization Registry

Influenza (2021–2022 season) and COVID-19 vaccination (including number of doses, respective dates, vaccine manufacturer), or absence thereof, were verified in the WIR. Vaccination status was assessed as of April 30, 2022. As previously described, the WIR is a statewide, electronic database that documents immunization records of Wisconsin residents.[15] The WIR captures 97% of vaccines administered in the state, including data from both public and private providers, and 98.5% of Wisconsin residents have an active WIR record. The WIR does not capture vaccines administered outside the state of Wisconsin; for this reason, residents of other states were excluded from the study. All vaccine providers are required to enter COVID-19 vaccine administration into the WIR, which is directly incorporated into our institution's electronic medical record. At the time of this study, influenza and COVID-19 vaccines were available at University of Wisconsin clinics through primary care or immunization clinics, in addition to private pharmacies. While influenza vaccines were available, COVID-19 vaccines were not available at the University of Wisconsin Digestive Health Center.

OUTCOMES

The primary outcome was defined as receipt of 3 COVID-19 mRNA vaccine doses or the viral vector equivalent. Three doses may represent completion of the 3-dose primary series in those who are moderately to severely immunosuppressed or completion of the 2-dose series plus booster dose in non-immunosuppressed patients. Moderate-to-severe immunosuppression as defined by the ACIP includes patients on antimetabolites (eg, methotrexate, thiopurines), anti-TNFs, or systemic corticosteroids. Systemic immunosuppression was defined as administration of antimetabolites, anti-TNFs, ustekinumab, tofacitinib, and systemic corticosteroids as previously described.[7] The 3-dose viral vector equivalent was defined as receipt of (1) initial 2-dose mRNA vaccine series followed by a viral vector dose, (2) initial viral vector dose followed by an mRNA vaccine dose, or (3) initial viral vector dose followed by a subsequent viral vector dose. Secondary outcomes included identification of variables associated with incomplete vaccination, such as demographic (eg, age, gender, race/ethnicity, urban-rural status), clinical (eg, duration of IBD, type of IBD-directed therapy), and vaccine-related (eg, influenza vaccination) variables.

Table. COVID-19 Vaccination Status Organized by Characteristic Data

	<3 Doses[a] (n = 284)	3 Doses[a] (n = 728)	*P* value
Demographic Data			
Age [years]: median (IQR)	38 (28 – 52)	49 (36 – 64)	< 0.001
Gender [male]: n (%)	166 (58.5)	369 (50.7)	0.023
Race: n (%)			
American Indian/Alaska Native	0 (0.0)	7 (1.0)	< 0.001
Asian	3 (1.1)	12 (1.6)	
Black	21 (7.4)	14 (1.9)	
Native Hawaiian/Pacific Islander	0 (0.0)	1 (0.1)	
White	250 (88.0)	689 (94.6)	
Unspecified	10 (3.5)	5 (0.7)	
Hispanic/Latino: n (%)	10 (3.5)	9 (1.2)	< 0.001
Underrepresented minority[b]: n (%)	30 (10.6)	29 (4.0)	< 0.001
Rural-urban geodisparity category: n (%)			
Rural	110 (38.7)	192 (26.4)	< 0.001
Underserved	18 (6.3)	39 (5.4)	0.210
Area deprivation index: median (IQR)	4 (2-5)	2 (1-4)	< 0.001
Clinical data			
BMI: median (IQR)	26.6 (23.6 – 31.5)	26.6 (23.4 – 30.8)	0.640
Smoking: n (%)			
Never	188 (66.2)	454 (62.4)	0.310
Current	20 (7.0)	45 (6.2)	
Former	75 (26.4)	228 (31.3)	
Unspecified	1 (0.4)	1 (0.1)	
CCI: median (IQR)	0 (0 – 1)	1 (0 – 3)	< 0.001
Clinic appointments [2021]: median (IQR)	1 (1 – 2)	1 (1 – 2)	0.520
Crohn's disease: n (%)	148 (52.1)	400 (54.9)	0.420
Duration of IBD [y]: median (IQR)	10 (5 – 17)	12 (6 – 22)	< 0.001
Prior IBD surgery: n (%)	73 (25.7)	218 (29.9)	0.180
IBD-directed therapy: n (%)			
No therapy	28 (9.9)	60 (8.2)	0.160
Mesalamine monotherapy	60 (21.1)	207 (28.4)	
Vedolizumab monotherapy	19 (6.7)	56 (7.7)	
Vedolizumab combination therapy	1 (0.4)	4 (0.5)	
Azathioprine or mercaptopurine monotherapy	19 (6.7)	6 (0.8)	
Methotrexate monotherapy	1 (0.4)	2 (0.3)	
Anti-TNF monotherapy	88 (31.0)	194 (26.6)	
Anti-TNF combination therapy	21 (7.4)	50 (6.9)	
Ustekinumab monotherapy	14 (4.9)	30 (4.1)	
Ustekinumab combination therapy	1 (0.4)	3 (0.4)	
Tofacitinib therapy	1 (0.4)	8 (1.1)	
Systemic corticosteroid therapy	31 (10.9)	46 (6.3)	
Vaccination Data			
Influenza vaccination [2021-22]: n (%)	87 (30.6)	582 (79.9)	< 0.001
COVID-19 vaccine provider addressal: n (%)	93 (32.7)	246 (33.8)	0.750

Abbreviations: IBD, inflammatory bowel disease; BMI, body mass index; CCI, Charlson Comorbidity Index; TNF, tumor necrosis factor.

[a]Number of mRNA vaccine doses received, or viral vector equivalent

[b]Black, Native Hawaiian/Pacific Islander, American Indian/Alaska Native, Hispanic/Latino.

Statistical Analysis

In urban-rural analyses, pooled urban advantaged, urban, and urban underserved categories were compared to pooled rural advantaged, rural, and rural underserved categories. In advantaged-underserved analyses, pooled urban advantaged and rural advantaged categories were compared to pooled urban underserved and rural underserved, with urban and rural categories being excluded. Mann-Whitney U test, *t* test, and chi-square test were used for statistical analyses. A multivariable logistic regression was performed with the primary endpoint of receipt of 3 doses, which incorporated the following variables: age, gender, URM status, advantaged/underserved status, urban-rural status, ADI, BMI, smoking status, CCI, type of IBD, duration of IBD, systemic immunosuppression, moderate-to-severe immunosuppression, COVID-19 vaccine addressal by provider, and influenza vaccination. A P value < 0.05 was considered significant. Statistical analysis was performed using IBM Statistical Product and Service Solutions version 27 (IBM Corp, Armonk, New York).

Ethics

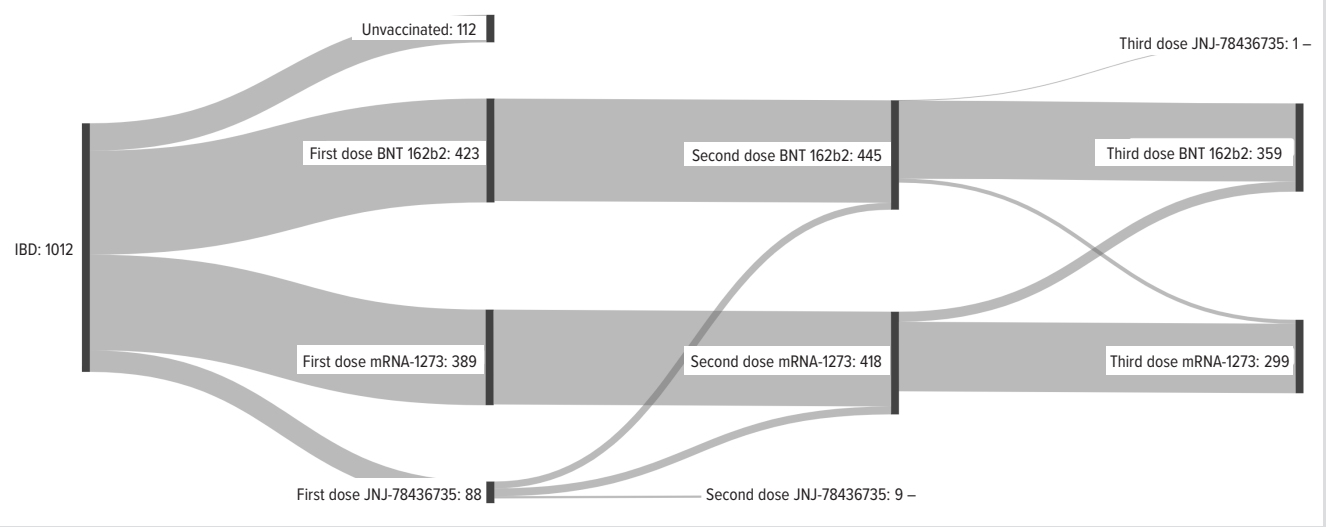
The study met the requirements for quality improvement as determined by the University of Wisconsin-Madison and was, therefore, deemed exempt from Institutional Review Board review.

RESULTS

A total of 1012 patients were identified (Table). Eight hundred ninety-one (88.0%) patients received the equivalent of 2 COVID-19 mRNA vaccine doses, and 728 (71.9%) patients received the equivalent of 3 doses (Figure). Five hundred twenty-nine patients were moderately to severely immunosuppressed. Three hundred sixty-seven (69.4%) immunosuppressed patients and 361 (74.7%) non-immunosuppressed patients received 3 doses ($P = 0.058$). The median time between doses 2 and 3 for immunosuppressed and non-immunosuppressed patients was 207 days (IQR 162-237) and 227 days (IQR 198–248), respectively ($P < 0.001$).

Among those who received more than 3 doses, compared to those who received 3 doses, the median age was lower (38 years [IQR 28-52] vs 49 years [IQR 36-64], $P < 0.001$), and there was a greater proportion of men (58.5% vs 50.7%, $P = 0.023$). Racial demographics were significantly different between both groups ($P < 0.001$), and among those who received less than 3 doses, there was a greater proportion of Hispanic/Latino patients (3.5% vs 1.2%, $P < 0.001$), URMs (10.6% vs 4.0%, $P < 0.001$), and rural patients (38.7% vs 26.4%, $P < 0.001$). The median ADI was higher among those who received less than 3 doses (4 [IQR 2-5] vs 2 [IQR 1-4], $P < 0.001$). Patients who received less than 3 doses had a shorter median duration (years) of IBD (10 [IQR 5-17] vs 12 years [IQR 6-22], $P < 0.001$), lower median CCI (0 [IQR 0-1] vs 1 [IQR 0-3], $P < 0.001$), and lower influenza vaccine uptake (30.6% vs 79.9%, $P < 0.001$). There was no difference in IBD-directed therapy as a whole ($P = 0.160$), but there was a trend

Figure. COVID-19 Vaccination Patterns in Patients With Inflammatory Bowel Disease (IBD)



Of the 88 initial viral vector recipients, 60 patients went on to receive an mRNA vaccine while 9 received another viral vector dose. Of the 803 patients who initially received 2 mRNA vaccine doses, 58 patients went on to do a mix/match strategy, one of whom pursued a viral vector vaccine.

(Figure created using SankeyMATIC.)

towards a greater proportion of patients with moderate-to-severe immunosuppression among those who received less than 3 doses (57.0% vs 50.4%, $P = 0.058$). There was no difference in vaccine addressal by provider (32.7% vs 33.8%, $P = 0.750$), which was low overall.

Multivariable logistic regression revealed that younger age (odds ratio [OR] 1.02; 95% CI, 1.01-1.03; $P = 0.001$), rural status (OR 3.44; 95% CI, 2.17-5.56; $P < 0.001$), URM status (OR 3.85; 95% CI, 1.89-7.69; $P < 0.001$), and absence of influenza vaccination (OR 8.17; 95% CI, 5.41-12.33; $P < 0.001$) were significantly associated with incomplete COVID-19 vaccination. The following variables did not contribute to the model: gender, advantaged/underserved status, ADI, BMI, smoking status, CCI, type of IBD, duration of IBD, systemic immunosuppression, moderate-to-severe immunosuppression, and COVID-19 vaccine addressal by provider.

DISCUSSION

This is the first US study to formally evaluate COVID-19 vaccine uptake in patients with IBD since the inception of the 3-dose series and booster dose. Vaccine uptake was again high, with 71.9% of our patient population receiving 3 doses. However, this rate is slightly lower than the 88% we observed for 2 doses, indicating that a relatively small subset of patients who did not receive interval doses exists, despite updated ACIP recommendations.[12] Moreover, in the approximate 1 year that passed between our initial study and this study, 2-dose uptake increased only from 84% to 88%. This small interval increase may indicate that most patients who intend to get vaccinated have done so already.

Basic statistical analyses identified the following variables as being associated with incomplete vaccination: age, gender, URM status, rural status, ADI, CCI, duration of IBD, and influenza vaccination. However, only the following variables remained significantly associated with incomplete vaccination following multivariable logistic regression: age, URM status, rural status, and influenza vaccination. These determinants of incomplete vaccination are similar to those reported in our initial study evaluating uptake of the original 2-dose primary series.[12] Additionally, these variables mirror risk factors observed at the national level with respect to the general population.[16–18]

While lower CCI and shorter duration of IBD were associated with incomplete vaccination using basic statistical analyses, this finding is likely the effect of confounding—we suspect due to age—given that these variables were no longer associated with vaccination following multivariable logistic regression, while age as a variable maintained statistical significance. Basic analyses also demonstrated a trend toward incomplete vaccination among those considered moderately to severely immunosuppressed; however, neither systemic immunosuppression nor moderate-to-severe immunosuppression significantly contributed to the multivariable logistic regression model. As we described previously, influenza vaccine uptake was again associated with COVID-19 vaccine uptake.[12] Addressal of COVID-19 vaccination status in a clinical note was found in only one-third of cases and was not associated with vaccination status; however, this lack of association may be an issue of statistical power given the relative infrequency of documented vaccine addressal.

While there is not yet published data describing uptake of 3 COVID-19 vaccine doses among patients with IBD in the US, similar work has been carried out elsewhere. Wellens et al

described uptake of a third COVID-19 vaccine dose among 733 patients with IBD receiving infliximab or vedolizumab at their 2 centers.[19] They found an uptake rate of 79.1%, with younger age, Crohn's disease, non-White ethnicity, and low socioeconomic status being associated with incomplete vaccination. These findings are similar to ours in that we both identified age and race/ethnicity to be a predictor of vaccination. However, we did not find type of IBD to be associated with vaccine uptake. Kuenzig et al, analyzing 107 059 patients with IBD residing in Ontario, Canada, reported a third dose uptake rate of 58.3%, with younger age being associated with incomplete vaccination.[20] While a significant strength of this study was the large sample size, it did not include relevant clinical information, such as medications. Finally, it should be noted that differences in vaccine uptake may be related to study timing relative to updated vaccine recommendations.

On September 1, 2022, the Centers for Disease Control and Prevention endorsed the ACIP's recommendation for vaccination with the updated bivalent COVID-19 booster for all adults.[21] Bivalent vaccines have been shown to reduce both incidence of COVID-related infection and death during Omicron circulation.[22] At the time of this manuscript preparation, according to Wisconsin Department of Health Services data, only 20.1% of eligible Wisconsin residents have received the bivalent booster, with similar disparities of age, gender, and race/ethnicity being observed.[23] At the national level, bivalent booster uptake has been reported as disproportionately low among underrepresented minorities and rural dwellers.[24] Some patient-cited reasons for incomplete vaccination have included lack of awareness of eligibility, perceived existing immunity from prior vaccination or infection, and concerns regarding safety, side effects, and efficacy.[25] While income and social vulnerability have been associated with incomplete vaccination, these variables are not associated with vaccine hesitancy, underscoring the importance of eliminating barriers to vaccine access at a structural level.[24] Finally, while provider recommendation is associated with increased bivalent booster vaccination rates, it is important to ensure that vaccine counseling is done consistently and in an equitable, systematic way.[24] In a recent study among unvaccinated adults "open" to vaccination, less than half received a provider recommendation for vaccination, and those who identified as "unsure" were even less frequently recommended vaccination.[24] Provider recommendation for vaccination in a culturally competent manner represents a practical and readily available intervention to increase vaccination rates in our patient population.

Both primary care physicians and gastroenterologists alike should address and strongly recommend COVID-19 vaccination to their patients with IBD, as doing so may improve vaccine uptake.[26] Vaccine addressal by the clinician has been shown previously to be positively associated with COVID-19 vaccine uptake.[27] Clinicians, including those caring for other immunosuppressed patient populations (eg, solid organ transplant, rheumatologic disease), may feel empowered to use our predictors of incomplete vaccination to identify patients who may benefit from additional discussion and education on the benefits of receiving a booster dose. Current trends suggest that implementation of updated boosters will become a regular occurrence, and, as such, integration of consistent and culturally competent vaccine messaging into the clinical workflow is apt to improve health outcomes and equity in our community.

Our study had several strengths. We included a large sample size of patients with IBD with a wide urban-rural geographic distribution, and we were able to confirm their vaccination status using a statewide immunization registry. Moreover, implementation of a multivariable logistic regression model allowed us to identify variables that were associated with incomplete vaccination. The study was limited in that it was a single-center, retrospective study that was not able to determine reasons for vaccine refusal nor accurately determine vaccine recommendations by providers. Moreover, the emphasis placed on vaccination at our center may have contributed to a relatively higher vaccination rate. Our academic center being located in an urban setting also likely contributed to our observed vaccination rate. We were also limited in the relatively small number of URMs in our patient population.

CONCLUSIONS

Receipt of 3 COVID-19 mRNA vaccine doses is high in patients with IBD. Younger age, underrepresented race/ethnicity, rural status, and lack of influenza vaccination are associated with incomplete COVID-19 vaccination. Further work is needed to evaluate uptake of additional doses and bivalent vaccine formulations, and there is a significant need for interventions to address disparities in vaccine uptake. Finally, COVID-19 vaccination, including administration of an updated booster dose, should continue to be addressed and recommended to our patients.

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